

### **REMARKS**

The above amendments to the above-captioned application along with the following remarks are being submitted as a full and complete response to the Office Action dated August 14, 2004. In view of the above amendments and the following remarks, the Examiner is respectfully requested to give due reconsideration to this application, to indicate the allowability of the claims, and to pass this case to issue.

#### **Status of the Claims**

Claims 3 – 11 are currently pending in this application, wherein claims 1 and 2 were previously withdrawn from consideration.

#### **Claim Rejections under 35 U.S.C. § 112**

Claims 3-11 stand rejected under 35 U.S.C. § 112 for failure to comply with the enablement requirement. Citing Enzo Biochem Inc., v. Calgene, Inc. (CAFC, 1999) 52 USPQ2d at 1135, the Examiner alleges that the instant specification has not taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The Examiner further asserts that the specification did not set forth starting materials and reaction conditions to the full extent of the claims' scope without having to resort to undue experimentation. In characterizing the invention, the Examiner stated that the claimed device clearly relates to performing nucleic acid hybridization reactions as well as performing amplification reactions. The Examiner then went on to discuss factors affecting hybridization reactions to the asserted conclusion that this invention has not enabled the full scope of hybridization reactions without undue experimentation. Applicants respectfully disagree with the Examiner and traverse as follows.

Contrary to the Examiner's assertions, applicants respectfully contend, as will be more fully developed below, that the specification is enabling with respect to the claims at issue; that there is considerable direction and guidance in the specification; that there was a high level of skill in the art at the time the application was filed; and that all of the methods needed to practice the invention were well known at the time of filing of the application. It would, therefore, not require undue experimentation to practice the full scope of this invention as claimed.

First, Applicants differ strongly with the Examiner's characterization of this invention. Claims 1 and 2 directed to a hybridization reaction method had been previously

withdrawn and are not currently reinstated. On the other hand, claims 3-11, now pending in this application are directed to hybridization devices. Thus, although claims 1 and 2, now withdrawn, sound in biochemical arts, claims 3-11 are directed to a mechanical contrivance for carrying out hybridization reactions. The applicant is not required to burden the application with details such as nucleic acid purity, probe chemistry, length of homologous sequences, ionic strengths, incubation temperature, nucleic acid concentration and so on, any more than the inventor of a test tube for carrying out chemical reactions is required to describe the physical and chemical conditions for carrying out the reactions.

As the Examiner is aware, hybridization of biopolymers simply involves contacting of biopolymer sequences under conditions that allow complementary sequences to anneal or hybridize. The invention of claims 3-11 is a simple and elegant means for bringing about said contacting. The conditions under which the contacting will promote a particular hybridization are left to the skill of the user. The fact that the devices of this invention will facilitate experimentation which can itself be undue, does not mean that the making and using of the full scope of this invention, on the basis of the instant disclosure, is itself subject to undue experimentation.

In effect, this invention is directed to a mechanical tool of limited parts for carrying out experiments. Similarly, the maker of a test tube for carrying out chemical reactions is only required to direct a user, to the extent that it is even necessary to do so, to bring about the contacting of reactants in the tube through the mouth of the test tube, such that the desired reaction would be contained in the test tube. The details of the ionic strength, concentration, volume, chemical properties and physical conditions of the reaction process is not of concern to the inventor, nor does the law intend that the specification be burdened with such details. Thus, in terms of characterization, the Examiner is requested to view this invention of claims 3 - 11 as a tool for carrying out hybridization experiments, much in the same way a test tube is a tool for carrying out chemical experiments. That a chemical experiment to be carried out in a test tube is undue, does not make the use of the test tube itself subject to undue experimentation.

Regarding how to make the claimed invention, it is well settled that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be

made does not render a claim invalid under 35 U.S.C. 112. Spectra - Physics, Inc. v. Coherent, Inc. , 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), cert. denied , 484 U.S. 954 (1987). The instant specification on pages 3 and 4 describes in detail how to make the claimed device. The drawings are also fully illustrative of a preferred embodiment of the device. The preferred dimensions of the device are also clearly stated on the first paragraph of page 4 of the instant specification. Applicants see nothing in the making of this invention that is subject to undue experimentation.

Regarding how to use the invention, it is also well settled that if a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112, is satisfied. In re Johnson , 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); In re Hitchings , 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also In re Brana, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993). The instant specification on page 2 teaches the dropping of a sample solution containing a sample biopolymer on a cover glass; and placing a slide glass having a probe biopolymer fixed thereon on the cover glass with fixed probe biopolymer facing down. Again, the Applicants see nothing undue about the rather simple act of dropping a sample of biopolymer on a cover glass to be covered by another cover glass containing a probe biopolymer. Requiring the Applicants to discuss the details of the chemical properties of the sample solutions and the probe sequences is beyond the requirements of the law.

Applicants believe that a skilled artisan, on the basis of what is taught in the specification, and what is known in the art at the time of filing the application, can make and use, without undue experimentation, the hybridization device of the present invention to carry out hybridization experiments.

Further, claims 3-11 stand rejected under 35 U.S.C 112, second paragraph for omitting essential structural cooperative relationships of elements, such a gap allegedly amounting to a gap between the necessary structural connections. The Examiner alleges that there is no structural connection between the cap, the cases, the film and the tray. The Examiner's principal contention is that since the claims at issue are drawn to a "device," that a structural connection must exist between all the embodiments of the invention, otherwise the claims must be drawn to a "kit" for which there is no requirement for structural connectedness of the various embodiments. Applicants respectfully disagree and now traverse as follows.

Applicants do not share the Examiner's specialized meaning of a "device" and a "kit." By implication, the Examiner purports to define a "device" as an "assembled kit" because the so called "structural connectedness" test would be met by an assembled kit. Applicants are not aware that "structural connectedness" is a judicially imposed test for a device. What Applicants believe, however, is that claim terms would be construed along the lines of their plain and ordinary meaning in light of the specification. Further, being their own lexicographers, if the specification warrants a departure from the plain and ordinary meaning of a term, then such departure is required for proper construction of the claims.

Where words in a patent claim have no specialized meaning to persons of skill in the art, the ordinary meaning of those words to those skilled in the art control the construction of the words, unless the evidence indicates that the inventor used them differently. Karlin Technology, Inc. v. Surgical Dynamics, Inc., 177 F.3d 968 (Fed. Cir. 1999).

In terms of plain and ordinary meaning, the English dictionary defines a device as "that which is formed or invented for a specific use." Similarly, a kit is defined as "a set or collection of tools or other objects for a special purpose." See Webster Dictionary of English Language. Applicants believe that the instant invention, directed to a hybridization device is more consistent with the plain and ordinary meaning of "device," than the Examiner's "structural connectedness" test. A hybridization device would necessary contain at least two separate components – the probe container and the sample container – to be contacted for hybridization test.

Whereas the Examiner sees the cap, the cases, the films, and the tray, as separate and distinct tools more appropriately comprising a kit, Applicants have elected to describe them as embodiments of the instant device for conducting hybridization and related tests. In particular, a hybridization kit would encompass not only the hybridization device of this invention, but also the droppers, probe readers, probe labels, reagents, sample preparation kit and so on necessary to carry out hybridization. Even then, rarely are the so-called devices every used by themselves. For instance, at what point does the detachable cap of a water bottle convert the bottle from a water-containing device to a water-containing kit? Is the Examiner contending that the cap even if specially made for that bottle, must always be affixed to the bottle whether or not there is water in the bottle in order to meet the test for a device? Applicants believe that the "structural connectedness" test for the Examiner's notion of a device applies only when the device is in use for the specific purpose for which it

was made. In that sense, Applicants argue that the embodiments of the instant hybridization device are structurally and functionally connected when in use.

With respect to the alleged omission of essential structural cooperative relationships of elements, Applicant's respectfully contend that the Examiner's basis of that assertion, namely, the erroneous construction of the claim elements, has been traversed by the foregoing. Even then, a tray provided with a hollow for placing a slide glass defines a structural relationship. A sheet for fixedly placing a cover glass onto an inner bottom of the tray in the hollow defines another structural relationship. Further, a case for accommodating the tray therein and a cap for sealing the tray within the case defines yet another structural relationship. Applicants are not aware of what the Examiner asserts to be missing in the mind of one skilled in the art in terms of how the different embodiments of this invention cooperate with each other.

If by structural relationship, the Examiner is insisting that all the embodiments must be mechanically linked prior to use in order for this device to be properly construed as a device, Applicants respectfully disagree with that notion and instead argue that even if the structural connectedness test of the Examiner were correct, the fact that all the embodiments of this invention are structurally linked while in use accords with the generally accepted meaning of that term. And to the extent that the usage of the term "device" in the claims is consistent with their understood meaning in the specification, Applicants have met the requirements of 35 U.S.C. § 112, second paragraph.

#### Conclusion

In view of the foregoing remarks, Applicants submit that there is no basis for applying the previous rejections to the pending claims and withdrawal of the rejections is respectfully requested. The claims are believed to be in condition for allowance, and Applicant earnestly solicits from the Examiner early notification of allowability.

Should the Examiner have any questions or believe a personal or telephonic interview may be in order, she is invited to contact the undersigned at his earliest convenience.

Respectfully submitted,

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